IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

TROY MITCHELL, Individually, and on Behalf of the Estate of Emma Mitchell ***Plaintiff,***	
v.	**Civil Action No. _____**
ADVANCED HCS, LLC d/b/a WEDGEWOOD NURSING HOME; WEDGEWOOD REHAB & NURSING GS, LLC; TOM GS, LLC ***Defendants.***	

DEFENDANTS' NOTICE OF REMOVAL TO FEDERAL COURT

TO THE HONORABLE COURT, PLAINTIFFS HEREIN, AND THEIR RESPECTIVE COUNSEL OF RECORD:

PLEASE TAKE NOTICE that Defendants Advanced HCS, LLC (incorrectly identified as Advanced HCS, LLC d/b/a Wedgewood Nursing Home); Wedgewood Rehab & Nursing GS, LLC; and TOM GS, LLC (collectively "Defendants"), file this Notice of Removal to Federal Court. This is a civil action over which this Court has original jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1442, and is one that may be properly removed to this Court pursuant to 28 U.S.C. § 1441. Pursuant to 28 U.S.C. § 1446(a), the Defendants assert the following grounds in support of their Notice of Removal:

I. PLEADINGS RELATED TO REMOVED CASE

1. This action was initially filed on or about December 23, 2020, in the 17th Judicial District Court of Tarrant County, Texas entitled *Troy Mitchell, Individually, and on Behalf of the Estate of Emma Mitchell v. Advanced HCS, LLC d/b/a Wedgewood Nursing home; Wedgewood Rehab & Nursing GS, LLC; and TOM GS, LLC;* Cause Number 017-322421-20.

2. Pursuant to Local Rule 81.1 of the Local Rules of the Northern District of Texas, the Civil Cover Sheet and Supplemental Cover Sheet are being filed with this Court as exhibits to this Notice of Removal. (*See* Exhibits A and B).

3. Further, pursuant to 28 U.S.C. §1446(a), true and correct copies of all process, pleadings and orders received by Defendant in the Judicial District Court action are attached. (*See* Exhibit C).

II. REMOVAL IS TIMELY

4. Defendants were served with Plaintiff's Original Petition on January 18, 2021. (*See* Exhibit C). Defendants filed their Original Answer on February 5, 2021 and their First Amended Answer on February 12, 2021. (*Id.*). Defendants are the only defendants named in the state court action. (*See* Exhibit C). This Notice of Removal is filed within thirty (30) days of service of the petition, therefore, the Notice is timely pursuant to 28 U.S.C. § 1446(b).

5. Concurrent with the filing of this Notice, Defendants are giving Plaintiff notice of this Notice of Removal pursuant to 28 U.S.C. § 1446(d) by filing this Notice electronically with the Clerk of Court through the ECF System; the ECF System will send a Notice of Electronic Filing to Plaintiff upon filing.

6. Defendants will also file a copy of this Notice of Removal with the 17th Judicial District Court of Tarrant County, Texas where the state court action is currently pending as required by 28 U.S.C. § 1446(d).

III. VENUE IS PROPER IN THIS COURT

7. Removal to the United States District Court for the Northern District of Texas, Fort Worth Division is proper because the state action was filed in the17th Judicial District Court of Tarrant County, Texas in Fort Worth, Texas as referenced in paragraph 1, above. Accordingly, this Court is the appropriate venue for filing this Notice of Removal pursuant to 28 U.S.C. § 1441(a) and 28 U.S.C. § 1446(a) because this district and division embraces the place in which the removed action was pending.

IV. JURISDICTION EXISTS UNDER 28 U.S.C. § 1331 BASED ON THE PREP ACT

8. This is a civil action over which the Court has original jurisdiction under 28 U.S.C. §§ 1331 and 1442(a) and is one that may be removed to this Court pursuant to 28 U.S.C. §§ 1441 and 1446 based on federal question and federal officer jurisdiction.

9. Plaintiff's Original Petition alleges that due to the wrongful acts and omissions of Defendants, Decedent, Emma Mitchell became infected with COVID-19 during her residency at Wedgewood Nursing Home and died in part due to the virus on May 8, 2020. (*See* Exhibit C-2, pg. 5, ¶ 21).

10. Plaintiff alleges Defendants are culpable for failing to institute a infection control program; failing to implement an infection control program; neglecting Decedent to such a degree that she was exposed to COVID-19 (in other words, Plaintiff seeks to hold Defendants liable for their decisions directly relating to the delivery, distribution, and dispensing of countermeasures to

combat COVID-19) and suffered pneumonia; failing to provide the medical and nursing care reasonably required for Decedent's known conditions; failing to provide the appropriate supervision and training to its staff and personnel that were providing Decedent care; and failing to implement an infection control plan under Federal and State law. Therefore, Plaintiff's claims fall under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d and 247d-6e (2006) ("PREP Act"), the applicability of which presents a significant Federal Question relating to the ongoing national emergency and COVID-19 pandemic. (*Id*. at pg. 5-6, ¶ 25; p. 6, ¶¶ 26).

11. The Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d, 247d-6e (2006) ("Prep Act"), and the Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020), are federal statutes that apply specifically to healthcare providers such as Defendants in the purchase, administration, dispensing, prescribing, distribution and use of countermeasures to prevent or mitigate the spread of COVID-19.

12. Because Plaintiff alleged a claim that arises under a federal statute, this Court has original jurisdiction pursuant to 28 U.S.C. § 1331.

13. Notwithstanding 28 U.S.C. § 1331, this Court is also specifically granted jurisdiction by 28 U.S.C. § 247d-6d(b)(8), which provides that no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or in in conflict with, any requirement applicable under this section" and relates to, among other things, use or administration of a covered countermeasure. In addition, 28 U.S.C. § 247d-6d(d)(1)&(e)(1) provide for exclusive Federal jurisdiction and an exclusive Federal cause of action for a suit against a covered person. Complete preemption exists when (1) the statute relied upon by defendant as preemptive contains civil enforcement provisions within the scope of which plaintiff's state law claims fall; and (2) there is

a clear indication of Congressional intention to permit removal despite the plaintiff's exclusive reliance on state law. *Railway Labor Executives Ass'n v. Pittsburgh & Lake Erie R.R.* Co. 858 F2d 936, 942 (3rd Cir. 1988) *citing Franchise Tax Bd. of State of Calif. v. Construction Laborers Vacation Trust for Southern Calif*., 463 U.S. 1, 24 (1983).

14. The Defendants' purchasing, administration, dispensing, prescribing, distribution, and use of countermeasures, such as facemasks and other personal protective equipment, and testing to prevent or mitigate the spread of COVID-19, which forms the basis of this action, presents a federal question under the PREP Act giving this Court original jurisdiction preempting all state law claims asserted by Plaintiff in the Original Petition 42 U.S.C. § 247d-6d. Further, Defendants and their staff were acting as qualified persons employed for the purpose of developing and implementing policies, procedures, and other countermeasures to prevent, limit, and/or control spread of COVID-19. Defendants and their staff are also covered persons authorized to administer FDA approved COVID-19 devices, tests, and medications use to treat the same.

15. The PREP Act provides liability protections for pandemic and epidemic products and security countermeasures. Specifically, 42 U.S.C. § 247d-6d(a)(1) empowers the Secretary of Health and Human Services (HHS) to issue a written declaration and provide that a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure during a health emergency. Further, the United States has submitted a Statement of Interest, pursuant to 28 U.S.C. § 517, supporting the position that the PREP Act preempts legal claims relating to the administration or use of covered countermeasures with respect to a public health emergency and, therefore, makes such claims removable from state

court. *See Bolton v. Gallatin Center for Rehabilitation & Healing, LLC*. Civil Action No. 3:20-cv-00683 (M.D. Tenn.).

16. On March 10, 2020, United States Health and Human Services Secretary, Alex M. Azar issued a Declaration invoking the PREP Act for the COVID-19 pandemic. The Declaration was effective as of February 4, 2020. (*See* Defendants' RFJN Exhibit E-2). Secretary Azar subsequently issued an Amended Declaration under the PREP Act, which was effective as of March 27, 2020. (*See* Defendants' RFJN Exhibit E-3). The Amendment added respiratory protective devices approved by NIOSH (National Institute for Occupational Safety and Health) as a covered countermeasure under the PREP Act. On June 4, 2020, Secretary Azar further amended the March 10, 2020 Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause. This Amendment was effective as of February 4, 2020. (*See* Defendants' RFJN Exhibit E-4). 85 Fed. Reg. 21012.[1]

17. On December 3, 2020, HHS Secretary Azar issued a Fourth Amended Declaration under the PREP Act, and made this Amended Declaration effective as of February 4, 2020. (*See* Defendants' RFJN Exhibit E-5).

18. The Secretary's Fourth Amended Declaration provides that "***COVID-19 is an unprecedented global challenge that requires a whole-of-nation response that utilizes federal-, state-, and local-distribution channels as well as private-distribution channels. Given the broad scale of this pandemic, the Secretary amends [Section VII of] the Declaration to extend PREP Act coverage to additional private-distribution channels*** . . . ." [Emphasis added.] (See Defendants' RFJN Exhibit E-5).

[1] See also Families First Coronavirus Response Act, H.R. 6201, 116th Cong. § 6005 (2020).

19. The Fourth Amended Declaration specifically provides that Section VII of the Declaration is amended to extend liability protection under the PREP Act to Covered Persons for Recommended Activities that are related to: "Covered Countermeasures that are:

> a. Licensed, approved, cleared or authorized by the FDA (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or
>
> b. A respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom."

(*See* Defendants' RFJN Exhibit E-5). 85 Red. Reg. 79196-97.

20. Secretary Azar's Fourth Amended Declaration further makes explicit that there can be situations where not administering a Covered Countermeasure to a particular individual can qualify as a decision relating to the administration of a countermeasure to an individual under the PREP Act. "Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections." (See Defendants' RFJN- Exhibit E-5). 85 Fed. Reg. 79194, 79197.

21. Secretary Azar's Fourth Amended Declaration further provides that "***the Declaration must be construed in accordance with the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) Advisory Opinions [of April 17, 2020 as modified on May 19, 2020 and October 22, 0220 as modified on October 23, 2020] on the Public Readiness and Emergency Preparedness Act and the Declaration ("Advisory Opinions"). The Declaration***

incorporates the Advisory Opinions for that Purpose." (*See* Defendants' RFJN Exhibit E-5). 85 Fed. Reg. 79192, 79194-95 (emphasis added).

22. Thus, the Fourth Amended Declaration incorporates all HHS Office of the General Counsel Advisory Opinions related to COVID-19 and the PREP Act into the Secretary's March 10, 2020 initiating Declaration. Beyond question, these Advisory Opinions must be given *Chevron* controlling weight. Where Congress has expressly delegated interpretive authority to an agency, that agency's interpretative proclamations are controlling on the federal courts. See *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 US 837, 843-844 (1984). Moreover, section (b)(7) of the PREP Act provides that "[n]o court of the United States, or of any state, shall have subject jurisdiction to review whether by mandamus or otherwise, any action by the Secretary under this subsection."

23. The Fourth Amended Declaration directly acknowledges the federal interests in cases which require interpretation and application of the PREP Act:

> "COVID-19 is a global challenge that requires a whole-of-nation response. **There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g.*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.**"

(*See* Defendants' RFJN Exhibit E- 5). 85 Fed. Reg. 79191, 79197 (emphasis added).

24. The Fourth Amended Declaration confirms the interpretation of the PREP Act is a matter of significant federal concern, and that removal of any case involving the interpretation of that Act is proper in accordance with the Supreme Court holding in *Grable*.

> The world is facing an unprecedented pandemic. To effectively respond, there must be a **more consistent** pathway for Covered Persons to manufacture, distribute,

> **administer** or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g.*, 545 U.S. 308 (2005), in having **a uniform interpretation of the PREP Act**.

(*See* Defendant's RFJN Exhibit E-5). 85 Fed. Reg. 79191, 79197 (emphasis added).

25. On January 8, 2021, HHS issued an Advisory Opinion which explains that the **"PREP Act is a 'Complete Preemption' Statute."** (See Defendant's RFJN Exhibit 1, emphasis added.) In addition, the Advisory Opinion explains that the **"Fourth Amendment to the Secretary's Declaration Supports the *Grable* Doctrine."** (*Id.*). The January 8, 2021 Advisory Opinion states "ordaining the metes and bounds of PREP Act protection in the context of a national health emergency *necessarily means that the case belongs in federal court*," pointing out that the Fourth Amendment to the Secretary's PREP Declaration concluded similarly. (*Id.*). Therefore, the Advisory Opinion advises that: "Once invoked, the court retains the case to decide whether the immunity and preemption provisions apply; if they do not apply, then the court would try the case as it would a diversity case. If the court finds, though, that the PREP Act applies, it would dismiss the case or if death or serious physical injury proximately caused by willful misconduct is alleged, transfer it to the District Court for the District of Columbia pursuant to 42 U.S.C. § 247d-6d(d)-(e)." (*Id.*).

26. The January 8, 2021 HHS Advisory Opinion provides that PREP Act immunity shall apply when a "covered person" is alleged to have failed to use a covered countermeasure to prevent the spread of COVID-19. The Advisory Opinion recognizes that "**District courts appear to have labored hard attempting to ordain whether the non-use of a covered countermeasure triggers the PREP Act and its complete preemption regime**." (*See* Defendant's RFJN Exhibit E-1, emphasis added). The Advisory Opinion states "the plain language of the PREP Act, which extends immunity to anything "relating to" the administration of a covered countermeasure,"

requires that"[p]rioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections." (*Id.*).

27. The HHS Secretary's Fourth Amendment to the PREP Act clarified that the Declaration must be construed in accordance with the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) Advisory Opinions on the PREP Act and the Declaration. (*See* Defendants' RFJN Exhibit E-5). The Declaration incorporates the Advisory Opinions for that purpose. (*Id.*). The PREP Act further provides the Secretary's actions pursuant to its authority to issue a declaration is immune from judicial review: No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection. 42 U.S.C. § 247d-6d(b)(7).

V. PREP ACT IN GENERAL

28. To qualify for liability immunity under the PREP Act, the healthcare provider must (1) meet the definition of a "Covered Person," (2) administer or use a "Covered Countermeasure," and (3) administer "Covered Countermeasures" during a "Recommended Activity" in relation to COVID-19. 42 U.S.C. § 247d-6d. Here, the PREP Act immunity applies preempting Plaintiff's state law claims because Defendants are a covered healthcare provider who qualifies as a person administering and/or using a covered countermeasure during the COVID-19 outbreak and emergency, and who qualifies as a program planner who supervises or administers a program with respect to the administration, dispensing, distribution, provision or use of a security countermeasure or a qualified pandemic or epidemic product, and provide a facility to administer or use a covered countermeasure to prevent and mitigate against the spread of COVID-19.

29. Defendants are "Covered Person" as contemplated by 42 U.S.C. § 247d-6d. In pertinent part, a "covered person" includes a person or entity that "is a qualified person who prescribed, administered, or dispensed" or is a program planner of COVID-19 Countermeasures and "an official, agent or employee of a person or entity therein described." 42 U.S.C. § 247d-6d(i)(2)(B)(iv) and (v). A "qualified person" is defined as a "licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed." 42 U.S.C. § 247d-6d(i)(8). In addition, Defendants qualify as program planners who supervise or administer a program with respect to the administration, dispensing, distribution, provision or use of a security countermeasure or a qualified pandemic or epidemic product, and provide a facility to administer or use a covered countermeasure to prevent and mitigate against the spread of COVID-19. 42 U.S.C. § 247d-6d(i)(6). Further, the PREP Act defines a "person" as an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state or local government agency or department." 42 U.S.C. § 247d-6d(i)(5).

30. Plaintiff's claims are preempted by the PREP Act. In this case, Plaintiff's allegations relate to the measures taken by the Defendants to prevent or mitigate the spread of COVID-19 and its' decision making related management and operation of its' countermeasures, including the use of facemasks and other personal protective equipment, medication, and testing. Defendants qualify as "covered persons" because Defendants are healthcare providers and/or owners/officers of licensed health professionals authorized to administer and/or use FDA approved medical devices such as facemasks and of gowns and other personal protective devices and testing to prevent or mitigate the spread of COVID-19. The PREP Act immunity in this action preempts all state law claims, and its applicability poses a "substantial federal issue," which would serve to clarify and

determine vital issues of law concerning the public health of the citizens of this country. The District Court, therefore, has original jurisdiction.

VI. THE PREP ACT APPLIES BECAUSE DEFENDANTS ARE COVERED PERSONS.

31. Immunity under the PREP Act is afforded to "covered persons" which include a person or entity that is a "program planner" of a covered countermeasure, and/or a qualified person who prescribed, administered, or dispensed such countermeasure. Under the Act, "person" includes "an individual, partnership, corporation, association, entity, or public or private corporation." 42 U.S.C. § 247d-6d(i)(2) and (5). The term "program planner" includes persons/entities "who supervised or administered a program with respect to the administration, dispensing, . . . provision, or use of a . . . qualified pandemic product or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a [HHS Secretary's] declaration . . . ." 42 U.S.C. §247d-6d (i)(6).

32. A private sector employer or other person can be a "program planner" when it carries out prescribed activities. (*See* Defendants' RFJN, Exhibit E-2) Fed. Reg., 85, No. 52, p. 15199. General Counsel for the Office of the Secretary of the Department of Health and Human Services issued a letter on August 14, 2020 which provides that a "senior living community" meets the definition of a "program planner" to the extent that it supervises or administers a program with respect to the administration, dispensing, distribution, provision or use of a qualified pandemic or epidemic product, including the provision to a facility to administer or use a covered countermeasure. (*See* Defendants' RFJN Exhibit E-6).

33. The broad definition of "program planner" was also addressed in Advisory Opinion 20-04, issued October 22, 2020. (*See* Defendants' RFJN Exhibit E-7).

34. Defendants were acting as a "program planner" and "qualified person." Wedgwood Nursing Center is a residential care facility for the elderly licensed by the Texas Health and Human Services, which employs licensed nursing personnel who are authorized to prescribe, administer, or dispense the covered countermeasures set forth in Plaintiffs' Complaint (i.e., PPE including facemasks, gloves, gowns, face shields, N95 masks, and COVID-19 testing) under the laws of the State of Texas.

35. Plaintiff's claims against Defendants include claims for medical negligence, corporate negligence, gross negligence, and wrongful death, among others. (*See* Exhibit C, generally). Each cause of action is based on Plaintiff's underlying theory that Defendants failed to exercise ordinary care to keep the premises, residents, and approaches safe by inadequately taking and enforcing precautions, providing, administering, and distributing inadequate personal protective equipment and devices. As referenced in Plaintiffs' Complaint, the precautions at issue concern Defendants failure to institute and implement an infection control program and neglecting Decedent to such a degree that she was exposed to COVID-19. Said infection control program necessarily involves the use of personal protective equipment and cohorting and testing as a countermeasures to prevent or mitigate the spread of COVID-19. These are the precise measures mentioned in the PREP Act Directive issued to address COVID-19.

36. Federal jurisdiction is further appropriate as the state action "arises under" federal law and raises a substantial federal issue, actually disputed and substantial. (*See Grable & Sons Metal Prods. v. Darue Eng'g & Mfg.,* 545 U.S. 308 (2005). Further, the federal court in retaining jurisdiction would not disturb the balance of state and federal responsibilities. *Id.*

37. The PREP Act immunity in this action preempts all state law claims, and its applicability poses a "substantial federal issue," which would serve to clarify and determine vital issues of law concerning the public health of the citizens of this country. The District Court, therefore, has original jurisdiction.

VII. JURISDICTION EXISTS PURSUANT TO THE FEDERAL OFFICER REMOVAL STATUTE (28 U.S.C. § 1442(A)(1))

38. Removal is also proper under 28 U.S.C. § 1442(a)(1), which provides for removal when a defendant is sued for acts undertaken at the direction of a federal officer.

39. "Unlike the general removal statute, the federal officer removal statute [Section 1442(a)] is to be 'broadly construed' in favor of a federal forum." *Durham v. Lockheed Martin Corp.,* 445 F.3d 1247, 1252 (9th Cir. 2006) [noting the U.S. Supreme Court has held the right of removal is "absolute" for conduct performed under color of federal office, and "has insisted that the policy favoring removal 'should not be frustrated by a narrow, grudging interpretation of § 1442(a)(1).'"].

40. The case is removable pursuant to Section 1442(a) because all requirements for removal under § 1442(a)(1) are satisfied here.

41. Defendants are "persons" under the federal officer removal statute pursuant to Section 1442(a)(1). *Goncalves v. Rady Children's Hosp. San Diego,* 865 F.3d 1237, 1245 (9th Cir. 2017); 1 U.S.C. § 1 [word "person" includes corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals]; *Bourgeois v. Huntington Ingalls Inc.*, No. 20-1002, 2020 U.S. Dist. LEXIS 84888 (E.D. La. 2020).

42. The "acting under" requirement, like the federal removal statute overall, is to be "liberally construe[d]" to cover actions that involve "an effort to assist, or to help carry out, the federal

supervisor's duties or tasks." *Goncalves v. Rady Children's Hosp. San Diego,* 865 F.3d at 1247; *Ruppel v. CBS Corp.,* 701 F.3d 1176, 1181 (7th Cir. 2012) quoting *Watson v. Philip Morris Cos., Inc.,* 551 U.S. 142 (2007); see also *Defender Ass'n,* 790 F.3d 457, 468 (3d Cir. 2015).

43. To satisfy the second requirement ("acting under" a federal officer) "a private persons actions 'must involve an effort to assist, or to help carry out, the duties or tasks of the federal superior.'" *Watson,* 551 U.S. at 152. Federal courts "have explicitly rejected the notion that a defendant could only be 'acting under' a federal officer if the complained-of conduct was done at the specific behest of the federal officer or agency." *Papp v. Fore-Kast Sales Co.,* 842 F.3d 805, 813 (3d Cir. 2016). This requirement, too, is to be liberally construed. *Watson,* 551 U.S. at 152.

44. "[R]emoval by a 'person acting under' a federal officer must be predicated upon a showing that the acts that form the basis for the state civil or criminal suit were performed pursuant to an officer's direct orders or to comprehensive and detailed regulations. *Cf. Bakalis v. Crossland Savings Bank,* 781 F. Supp. 140, 144-145 (E.D.N.Y. 1991) ('The rule that appears to emerge from the case law is one of 'regulation plus ...'.")." *Ryan v. Dow Chemical Co.,* 781 F. Supp. 934, 947 (E.D.N.Y. 1992) "This control requirement can be satisfied by strong government intervention and the threat that a defendant will be sued in state court 'based upon actions taken pursuant to federal direction.'" See *Fung v. Abex, Corp.,* 816 F. Supp. 569, 572 (N.D. Cal. 1992). The "acting under" requirement is met when Defendants are acting pursuant to detailed and ongoing instructions from a federal officer. *Winters v. Diamond Shamrock Chem. Co.,* 149 F.3d. 387 (5th Cir. 1998).

45. Prior to the current national pandemic, regulation of nursing homes was very general in nature. In 1987, Congress enacted legislation, known as the Nursing Home Reform Act, requiring nursing homes participating in Medicare and Medicaid to comply with certain quality of care rules and regulations. *See* 42 U.S.C. § 1396r, 42 U.S.C. §1395i-3 and 42 C.F.R. § 483.1 through 42

C.F.R. § 483.95. The Centers for Medicare and Medicaid Services ("CMS"), contracts with state surveyors, including the Texas Health and Human Services ("HHS"), to perform federal surveys to ensure that facilities accepting Medicare and Medicaid payments comply with federal laws and regulatory requirements. Generally, and prior to the pandemic, these surveyors conducted site visits to evaluate whether facilities are in compliance with federal requirements and regulations. *See* 42 U.S.C. § 1395aa; and 42 CFR § 488.10. If HHS surveyors found a "deficiency" in a facility's compliance with federal regulations, HHS would issue a deficiency or citation, and on occasion use the CMS enforcement remedy of a "directed plan of correction," under which the facility would develop and submit a plan of correction, which would then be enforced on behalf of CMS by HHS.

46. In January 2020, in response to the pandemic and the national state of emergency, CMS and the CDC, began issuing detailed directives to healthcare facilities as part of the coordinated national effort to respond to and contain the COVID-19 pandemic. HHS surveyors, contracted by CMS, were supervising skilled nursing facilities with respect to all aspects of infection control and the pandemic response and ensuring strict compliance with the CMS directives. The issuance of in time and evolving guidance in response to a public health emergency was in contrast to the role of CMS before the pandemic. Prior to the pandemic, the focus was on ensuring compliance with existing regulations. However, throughout the pandemic, CMS and HHS as its agent, specifically instructed facilities to take or not take particular clinical and operational actions in the absence of finding deficiencies that would otherwise require the facility to develop its own plan of correction. These directives included the following:

A. Early directives to skilled nursing facilities focused on monitoring residents and staff for symptoms and protecting healthcare providers from infection due to contact with

symptomatic patients. Facilities were advised to adhere to standards for infection prevention and take steps to prepare for COVID-19.

B. In January and February, 2020, the CDC issued a number of health updates regarding COVID-19, as well as criteria to guide the evaluation and testing of patients under investigation ("PUI") for COVID-19. Healthcare providers were advised to identify PUI based on clinical features, travel to an affected geographic region, and contact with a person confirmed to have tested positive for COVID-19. Persons meeting the PUI criteria were to be tested and healthcare providers were advised to immediately notify their local or state health department in the event they were evaluating a PUI. State health departments in turn were instructed to immediately contact the CDC and complete a PUI case investigation form. Initially COVID-19 testing was conducted solely through the CDC. The CDC also instructed healthcare providers to use standard, contact and airborne precautions when interacting with PUI. (See Defendants' RFJN, Exhibits E-10, E-11, and E-12).

C. On February 1, 2020, the CDC issued an "Update and Interim Guidance on the Outbreak of 2019 Novel Coronavirus" to provide further guidance to healthcare providers regarding 2019-nCoV 2019 (the 2019 Novel Coronavirus, now known as COVID-19). ***The guidance was part of the "ongoing US public health response . . . to identify and contain [the] outbreak and prevent sustained spread of 2019-nCoV in the United States"*** and addressed infection prevention and control specific to 2019-nCoV. (emphasis added). The CDC noted that the first United States case was identified on January 21, 2020, and had recently traveled from Wuhan, China. The CDC provided updated directives related to screening of patients in healthcare facilities, and coordination with local health departments for testing and reporting of results. The Update set forth the criteria for assessing patients for COVID-19. Persons with a confirmed or suspected COVID-19 infection who were hospitalized were to be evaluated and cared for in a private room with the door closed, ideally an airborne infection isolation room. (*See* Defendants' RFJN, Exhibit E-13).

D. On February 6, 2020, CMS began preparing healthcare facilities for the national response to the emerging 2019 Novel Coronavirus by issuing a Memorandum to State Survey Agency Directors (i.e., "CDPH"). The memo directed healthcare providers to adhere to CDC directives regarding the use of standard, contact and airborne precautions when interacting with PUI and advised facilities to have PPE measures and protocols in place. (*See* Defendants' RFJN, Exhibit E-14).

E. On February 28, 2020, the CDC issued a Health Update and Interim Guidance on the Outbreak of 2019 Novel Coronavirus (COVID-19) for healthcare providers. The Update noted to date there had been limited spread in the United States. As of February 26, 2020, there were a total of 61 cases in the country, 46 of whom were repatriated person from high-risk settings. The guidance again included criteria to guide the evaluation and testing of PUI for COVID-19. This update further added patients with fever and signs/symptoms of lower respiratory illness without an alternative explanatory diagnosis and no identified source of exposure to the list of those who should be tested. At this time, testing was being performed at state public health laboratories and the CDC. (*See* Defendants' RFJN Exhibit E-15).

G. On or about March 3, 2020, the CDC issued "Strategies to Prevent the Spread of COVID-19 in Long-Term Care Facilities (LTCF)." This publication, issued specifically to facilities like Wedgewood Nursing Center, reiterated that standard, contact and droplet precautions with eye protection were to be used in the care of residents with an undiagnosed respiratory infection. Facilities were advised to make PPE, including facemasks, eye protection, gowns, and gloves available immediately outside the resident's room and to post signs on the door or wall outside the room of the residence to clearly describe the type of precautions needed and the required PPE. (*See* Defendants' RFJN Exhibit E-16).

H. On March 4, 2020, CMS issued a Memorandum to State Survey Agency Directors regarding Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in nursing homes. The State Survey Agency, as agent for CMS, was also responsible for

disseminating the contents of the QSO memo to the States' nursing homes. Facilities were to screen visitors for international travel, symptoms of respiratory infection, and contact with someone with or under investigation for COVID-19, and to restrict entry of visitors who meet these criteria. Facilities were advised to screen staff for the criteria as well, and that staff who meet the criteria should not report to work. The CMS guidance also included directions as to when to transfer a resident with a suspected or confirmed COVID-19 infection to a hospital, and under what conditions a nursing home may accept patients diagnosed with COVID-19. CMS advised facilities to follow the available CDC guidance regarding infection prevention and control. (*See* Defendant's RFJN Exhibit E-17).

I. On March 8, 2020, the CDC issued further Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19). The CDC advised that with the expanding spread of COVID-19, additional areas of geographic risk were being identified and the criteria for considering testing were being updated to reflect this spread. The Update indicated that additional COVID-19 testing was becoming available in clinical laboratories and the CDC had been specifically directing which persons could be tested. (*See* Defendants' RFJN Exhibit E-18).

J. On March 10, 2020, the CDC issued Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings. The publication reiterated the directive regarding use of standard and transmission-based precautions, and directed healthcare providers who enter the room of a patient with known or suspected COVID-19 to adhere to standard precautions and use a respirator or facemask, gown, gloves and eye protection. The CDC advised that patients with known or suspected COVID-19 should be cared for in a single-person room with the door closed. Airborne infection isolation rooms were to be reserved for patients undergoing aerosol generating procedures. This CDC publication also noted that "[m]ajor distributors in the United States have reported shortages of PPE, specifically N95 respirators, facemask and gowns." Based on a local

and regional shortages of PPE, the CDC advised that facemasks were an acceptable alternative when the supply chain of respirators cannot meet the demand. Facilities were instructed to prioritize respirators for situations where respiratory protection is most important. The CDC further advised that in the event of a shortage of medical gowns, gowns should also be prioritized for aerosol generating procedures. (*See* Defendants' RFJN Exhibit E-19).

K. On March 10, 2020, CMS issued a Memorandum providing an update regarding the PPE recommendations issued by the CDC on March 10. (*See* Defendants' RFJN Exhibit E-20).

L. On March 13, 2020, President Trump declared the COVID-19 outbreak a national emergency. Following this proclamation, the CDC and CMS took swift action to waive restrictions and expand capacity for healthcare providers and suppliers to coordinate the national response to the nationally declared state of emergency. On March 13, 2020, CMS issued revised infection control and prevention directives for nursing homes to prevent the transmission of COVID-19. In the Memo, facilities were ordered to restrict visitation of all visitors and non-essential health care personnel, cancel communal dining and all group activities, implement active screening of residents and staff for fever and respiratory symptoms, and screen all staff at the beginning of their shift for fever and respiratory symptoms. Facilities were ordered to continue to follow applicable CDC guidelines. (*See* Defendants' RFJN Exhibit E-21).

M. On March 17, 2020, the CDC issued documents containing instructions to optimize the supply of PPE such as eye protection, isolation gowns, N95 respirators and face masks. For facilities in contingency capacity, the CDC advised that extended use of facemasks should be implemented and that the use of facemasks should be restricted for use by healthcare providers rather than patients for source control. During crisis capacity, facilities were to prioritize facemasks for use during activities where prolonged face-to face or close contact with a potentially infectious patient is unavoidable, exclude healthcare providers at higher risk for severe illness from COVID-19 from contact with known or suspected COVID-19 patients, use

a face shield with no mask, and in settings where facemasks were not available, use homemade masks. In the document pertaining to optimizing the use of N95 respirators, the CDC advised that (1) if the healthcare provider was to remain 6 feet away from a symptomatic patient, no facemask or N95 respirator was required; (2) if the healthcare provider was to be within 3 to 6 feet of a symptomatic patient, a facemask should be used; and (3) if the healthcare provider was to be within 3 feet of a symptomatic patient including providing direct patient care, an N95 respiratory should be used if available. When an N95 respirator was not available, healthcare providers were instructed to wear a surgical mask and exclude healthcare providers at higher risk from severe illness from contact with an infectious patient.(*See* Defendants' RFJN Exhibit E-22).

N. On March 20, 2020, CMS issued a memo entitled Prioritization of Survey Activities. In the memo, CMS advised that CMS surveyors would be conducting targeted infection control surveys of providers identified in collaboration with the CDC and the HHS Assistant Secretary for Preparedness and Response to ensure providers are implementing actions to protect the health and safety of individuals to respond to the COVID-19 pandemic. A skilled facility would be subject to citation, and fines for failure to implement the directives from CMS. **Thus, the directives from CMS (which followed and instructed facilities to follow the CDC guidance) were truly mandates**, not recommendations. (*See* Defendants' RFJN Exhibit E-23).

O. On March 21, 2020, the CDC issued further guidance specifically aimed at long term care facilities entitled "Preparing for COVID-19: Long-term Care Facilities Nursing Homes." In this publication, nursing homes were advised to restrict visitation, restrict all volunteers and nonessential healthcare personnel, cancel group activities and communal dining, implement active screening of residents and healthcare providers for fever and respiratory symptoms, and make PPE available in areas where resident care is provided and place a trash can near the exit inside the resident's room so staff can discard PPE prior to exiting. The CDC further directed that "residents with known or suspected COVID-19 do not need to

be placed in an airborne infection isolation room (AIIR) but should ideally be placed in a private room with their own bathroom. Room sharing might be necessary if there are multiple residents with known or suspected COVID-19. As roommates of symptomatic residents might already be exposed, it is generally not recommended to separate them in this scenario." (*See* Defendants' RFJN Exhibit E-24).

P. On April 2, 2020, CMS issued new guidelines directed towards long-term care facilities to "mitigate the spread" of COVID-19. CMS noted that "[l]ong-term care facilities are a critical component of America's healthcare system…In recent weeks, CMS and CDC, at President Trump's direction have worked together to swiftly issue unprecedented targeted direction to the long-term care facility industry, including a general prohibition of visitors implemented on March 13, 2020, as well as strict infection control and other screening recommendations." CMS and the CDC were providing "critical, needed leadership for the Nation's long-term care facilities to prevent further spread of COVID-19" and that long term care facilities were to immediately implement symptom screening for all persons (residents, staff, visitors, outside healthcare workers, vendors, etc.) entering a long term care facilities. Facilities were ordered to specifically ask about COVID-19 symptoms and to check the temperature of all visitors, as well as limit access points and ensure that all accessible entrances have a screening station. Every resident was also to be assessed for symptoms and have their temperature checked every day, and patients and residents entering facilities screened for COVID-19 through testing, if available. CMS ordered facilities to ensure all staff are using appropriate PPE when interacting with residents to the extent PPE is available and per CDC guidance on the conservation of PPE. CMS further directed long term care facility staff to wear a facemask while in the facility for the duration of the state of emergency, to wear full PPE for the care of any resident with known or suspected COVID-19, and if COVID-19 transmission occurs in the facility, healthcare personnel were to wear full PPE in the care of all residents irrespective of COVID-19 diagnosis and symptoms. Further, to avoid transmission within long-term care facilities, the facilities were

advised to use separate staffing teams for COVID-19 positive residents to the best of their ability, and to work with State and local leaders to designate separate facilities or units within a facility to separate COVID-19 negative residents from COVID-19 positive residents and individuals with unknown COVID-19 status. (*See* Defendants' RFJN Exhibit E-25).

47. Through the federal directives issued by the CDC, CMS, and the HHS surveyors contracted by CMS, federal authorities were making the operational decisions as it related to the clinical pandemic response in skilled nursing facilities. Facilities were ordered to restrict visitation, cancel communal dining, implement active screening and staff for fever and respiratory symptoms, screen staff at the beginning of their shift for fever and respiratory symptoms and actively take their temperature and document the absence of shortness of breath and any new or change in cough and sore throat. Facilities were instructed on which patients and staff to test for COVID-19, under what circumstances to use and how to conserve PPE, when to permit staff who had COVID-19 to return to work, and how to handle the isolation of residents infected with COVID-19 and those under investigation for COVID-19. These very detailed clinical directives and instructions represented a marked departure from the regulatory structure which existed before the pandemic. Moreover, as acknowledged by Health and Human Services Secretary Alex Azar in his Fourth Amended Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19: "COVID-19 is an unprecedented global challenge that requires a whole-of-nation response that utilizes federal-, state- and local-distribution channels as well as private-distribution channels (See Defendants' RFJN Exhibit E-5).

48. At all relevant times Wedgewood Nursing Home was acting at the specific direction of federal authorities to address the on-going federal effort and national state of emergency to contain the COVID-19 pandemic, and prevent the spread of the virus. All actions taken by Wedgewood Nursing Home in preparation for and response to the COVID-19 pandemic, were taken "in an effort to assist, or help carry out, the duties or tasks" as ordered by the CDC and CMS, and HHS

surveyors (per the contract with CMS), and performed pursuant to the direct orders and comprehensive and detailed directives issued by these agencies. Wedgwood Nursing Home was acting at the direction of the federal government to prevent, treat and contain COVID-19 at the facility and in its care and treatment of Emma Mitchell.

49. Defendants can establish a causal nexus between Plaintiff's claims and the actions it took were under federal direction. *Winters v. Diamond Shamrock Chemical Co*., 149 F.3d 387, 398 (5th Cir. 1998). Here, Plaintiff alleges that due to the wrongful acts and omissions of Defendants, Decedent, Emma Mitchell became infected with COVID-19 during her residency at Wedgewood Nursing Home and died in part due to the virus on May 8, 2020. (*See* Exhibit C-2, pp. 5, ¶ 21). Defendants' response to the COVID-19 pandemic as it relates to the claims of Plaintiff (i.e., the care and treatment of Emma Mitchell) was directly related to the orders and directives issued by the federal government. There is a clear causal nexus between the claims against Defendants and the actions taken by Defendants at the direction of the federal government including, but not limited to, the direction of CDC, CMS, as well as by representatives of HHS, the State Survey Agency acting under contract with CMS, with respect to the response to the pandemic at the facility and the administration of care to Emma Mitchell. The nexus element is met as Defendants were following the orders/directives of CMS with regard to infection control, COVID-19 testing and the use of PPE.

50. Defendants also meets the requirement to assert colorable federal defenses. For purposes of removal, the defense must be "colorable" and need not be "clearly sustainable" as the purpose for the removal statue is to secure the validity of the defense may be tried in federal court. *Willingham v. Morgan*, 395 U.S. 402, 407 (1969). The colorable federal defense element is met where a defendant alleges its actions were justified as the defendant was complying with federal

directives with respect to the alleged wrongful acts. See *Venezia v. Robinson*, 16 F.3d 209, 212 (7th Cir. 1994); and *Mesa v. California*, 489 U.S. 121, 126-127. See also *Rural Community Workers Alliance v. Smithfield*, 2020 WL 2145350 (W.D. Mo.) finding that compliance with federal guidelines aimed to protect employees from COVID-19 exposure served as a defense to civil liability. Here, Defendants were complying with Federal directives and regulations issued by CMS, the CDC, and HHS, the CMS contracted state surveyors, in responding to all aspects of the COVID-19 pandemic.

51. As a colorable defense, Defendants also assert an immunity defense under the PREP Act as set forth at 42 U.S.C. 247d-6d(a)(1). This Act provides for immunity of "covered persons" from "suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of covered countermeasure" provided there has been a declaration issued by the Secretary of Health and Human Services with respect to such countermeasure. On March 10, 2020, United States Health and Human Services Secretary Alex M. Azar issued a Declaration invoking the PREP Act for the COVID-19 pandemic. The Declaration was effective as of February 4, 2020. (*See* Defendants' RFJN Exhibit E-2). Defendants are a "covered person" under the act.

52. Under the PREP Act and Secretary Azar's initial Declaration, "covered countermeasures" include any qualified pandemic or epidemic product; and any drug, biologic product or device. Secretary Azar's Declaration also included as covered countermeasures "any antiviral drug, any biologic, any diagnostic, any other device or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product. . ."

53. In the initial Declaration, Secretary Azar declared that "Administration of Covered Countermeasures means physical provision of the countermeasures to recipients, ***or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures***." [Emphasis added.]

54. Secretary Azar subsequently issued an Amended Declaration under the PREP Act, which was effective as of March 27, 2020. (*See* Defendants' RFJN Exhibit E-3). The Amendment added respiratory protective devices approved by NIOSH (National Institute for Occupational Safety and Health) as a covered countermeasure under the PREP Act. In the Amendment, the Secretary stated that "any respiratory protective devices approved by NIOSH . . . is a priority for use during the public health emergency that [the Secretary] declared on January 31, 2020 . . . for the entire United States to aid in response of the nation's health care community to the COVID-19 outbreak."

55. On June 4, 2020, Secretary Azar further amended the March 10, 2020 Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause. This Amendment was effective as of February 4, 2020. (*See* Defendants' RFJN, Exhibit E-4).

56. Plaintiff's Complaint alleges that Defendants failed to prevent Decedent, Emma Mitchell from contracting COVID-19. Such claim by its nature relates to Defendants' administration and/or use of covered countermeasures and qualified pandemic products including PPE, and COVID-19 testing kits, used to diagnose, mitigate, prevent, treat or cure COVID-19 or to limit the harm COVID-19 might otherwise cause, and therefore falls under the PREP Act. 42 U.S.C. §§ 247d-6d and 247d-6e (2006), which provides Defendants with immunity for such claims. In addition, as

further clarified by the Secretary's Fourth Amended Declaration and the January 8, 2021 HHS Office of General Counsel Advisory Opinion, the PREP Act may apply to non-use of covered countermeasures as well as use. (*See* Defendants' RFJN Exhibit E-5, at pp. 79196-79197, 9 at pp. 2-4). Thus, the claims in Plaintiffs' Complaint relate to "covered countermeasures" under the PREP Act, which qualify for and trigger immunity from liability for the claims in this action.

57. The PREP Act is applicable with respect to a "covered countermeasure," which definition includes: "(1) a qualified pandemic or epidemic product (as defined in § 247d-6d (i) (7)) . . . or (4) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health ("NIOSH") and that the Health and Human Service Secretary determines to be a priority for use during a public health emergency declared under section 247d." 42 USC § 247d-6d (i) (1). A "qualified pandemic or epidemic product" is defined as: a drug, biologic product or device that is:

> "(A)
> (i) a product manufactured, used, designed, developed, modified, licensed, or procured—
> (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
> (II) to limit the harm such pandemic or epidemic might otherwise cause
> (ii) a product, manufacture, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious of life-threatening disease or condition caused by a product described in clause (i);or
> (iii) a product or technology intended to enhance the use or effect of a drug, biologic product, or device described in clause (i) or (ii); and
>
> (B)
> (i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 262 of this title;
> (ii) the object of research for possible use as described in subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or
> (iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug and Cosmetic Act."

See 42 USC § 247d-6d (i)(7).

58. The Department of Health and Human Services Office of the Secretary, issued an omnibus advisory opinion on April 17, 2020, to address questions and concerns regarding the scope of the PREP Act immunity for the COVID-19 pandemic. The Opinion summarized the requirements to meet the definition of a qualified pandemic or epidemic product noting that the product:

> (1) must be used for COVID-19; and
> (1) must be
> (a) approved, licensed, or cleared by FDA;
> (b) authorized under an EUA [emergency use authorization];
> (c) described in an EUA [emergency use instructions]; or
> (d) used under either an Investigational new Drug (IND) application or an Investigational Device Exemption."

(*See* Defendants' RFJN, Exhibit E-8, p. 4).

59. Moreover, attached as Appendix A to this Advisory Opinion is a list of the "covered countermeasures" for which emergency use authorizations have been issued by the United States Food and Drug Administration. (*See* Defendants' RFJN, Exhibit E-9). The list includes twelve pages of COVID-19 test kits, and provides that face shields, gowns, shoe covers, non-surgical isolation gowns, surgical caps, properly labeled non-surgical masks, and certain non-NIOSH approved respirators are covered by an EUA. Surgical masks are not listed; however, such masks are Class II medical devices which are cleared by the FDA for use. (See 21 CFR 878.4040). Thus, COVID-19 testing kits, face masks, gowns, gloves and other PPE are "qualified pandemic or epidemic products" and "covered countermeasures" under the PREP Act, as such products are either FDA cleared/approved or are included in an EUA.

VIII. PREP ACT IMMUNITY APPLIES WHERE THERE IS A CAUSAL CONNECTION BETWEEN THE USE AND ADMINISTRATION OF COVERED COUNTERMEASURES BY DEFENDANTS, A COVERED PERSON

60. Immunity under the PREP Act "applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the . . . distribution . . . purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." [Emphasis added.] 42 USC § 247d-6d (a)(2)(B).

61. Plaintiff alleges that Defendants failed to prevent Decedent, Emma Mitchell, from contracting COVID-19. Such claim by its nature arises out of Defendants use, distribution, procurement and administration of covered countermeasures/qualified pandemic products used to diagnose, mitigate, prevent, treat or cure the COVID-19 virus, or to limit the harm COVID-19 might otherwise cause thereby triggering application of the PREP Act.

62. The following are an exemplary, but in no way complete list of some of the detailed directives and regulations issued by the HHS, CMS, and the CDC to specifically compel healthcare providers and nursing homes like Defendants to assist in the national effort to respond to the COVID-19 pandemic.

63. In Section IX of his March 10, 2020 Declaration, Secretary Azar defines "administration of a covered countermeasure" as the "physical provision of the countermeasures to recipients ***or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients***; ***management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures***." (emphasis added). (*See* Defendants' RFJN Exhibit E-2).

64. Under the PREP Act, the Secretary may specify that liability protections are in effect only for Covered Countermeasures obtained through a particular means of distribution. Section VII of Secretary Azar's initial March 10, 2020 Declaration provided that "liability immunity is afforded to Covered Persons only for Recommended Activities that are related to (a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or (b) Activities authorized in accordance with public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency." (*See* Defendants' RFJN Exhibit E-2).

65. Secretary Azar's Fourth Amended Declaration amended Section VII of the Declaration. This Fourth Amendment provides that "***COVID-19 is an unprecedented global challenge that requires a whole-of-nation response that utilizes federal-, state-, and local-distribution channels as well as private-distribution channels. Given the broad scale of this pandemic, the Secretary amends [Section VII of] the Declaration to extend PREP Act coverage to additional private-distribution channels*** . . . ." [Emphasis added.] (*See* Defendants' RFJN Exhibit E-5).

66. The Fourth Amended Declaration specifically provides that Section VII of the Declaration is amended to extend liability protection under the PREP Act to Covered Persons for Recommended Activities that are related to: "Covered Countermeasures that are:

> i. Licensed, approved, cleared or authorized by the FDA (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or
>
> ii. A respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be priority for use during a public health emergency declared under section 319 of the PHS Act to

> prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom."

(*See* Defendants' RFJN Exhibit E-5, pp. 22-23).

67. The PREP Act was designed to apply to individuals and entities responding to public health emergencies, and provides immunity for claims involving "covered countermeasures" under the Act. The broad definition of "administration of a covered countermeasure" set forth in Secretary Azar's declaration encompasses Defendants' plans and decisions with respect to how best to utilize and optimize supplies of PPE and COVID-19 testing kits, and whether and when the use of such countermeasures is appropriate. Moreover, during the relevant time frame to Plaintiff's claims, Defendants were subject to guidance/directives issued by the CDC, CMS, and the HHS, and was following this applicable public health guidance with respect to the use of PPE and COVID-19 testing. Defendants have thus established that it has immunity under the PREP Act as it relates to Plaintiffs' claims relating to deficiencies in the use of PPE or COVID-19 testing.

IX. THIS CASE RAISES IMPORTANT FEDERAL ISSUES GRANTING FEDERAL QUESTION JURISDICTION OVER THE MATTER

68. The healthcare community's response to this pandemic was coordinated at a national level by the Department of Health and Human Services, the CDC, the FDA and CMS, and entailed the issuance of detailed directives to healthcare providers to identify and sequester infected patients, which patients under investigation were to be tested, and the use of personal protective equipment. All cases positive for COVID-19 were reported to the CDC, and initially all testing was conducted solely through the CDC. This case involves issues of national importance related to Defendants' response to a national public health state of emergency, which has not been seen by this country in over a century. Plaintiffs' claims in this lawsuit invoke a substantial federal question regarding

the extent to which the broad immunities afforded under the PREP Act apply to Defendants' conduct.

69. The federal courts have a substantial interest in determining the application of the PREP Act in this matter. The PREP Act and its triggering immunity, has been invoked in exceptionally rare circumstances since it was enacted in 2005. The PREP Act and HHS Secretary Azar's declarations confer a broad and sweeping immunity to individuals and entities fighting the COVID-19 pandemic during this declared state of emergency. The unique character of the COVID-19 virus as well as its high communicability, required Secretary Azar to set forth an expansive declaration covering broad categories of measures to fight the pandemic including COVID-19 testing and PPE, all of which require interpretation as to the scope and application. Thus, there can be no doubt that there is a substantial and compelling interest for the PREP Act and the Secretary's declaration to be interpreted by the Federal Courts. Moreover, the Federal Court is uniquely and properly positioned to interpret Congressional intent and interests of the federal government.

70. This case also satisfies the second prong set forth in *Grable*. Federal jurisdiction over Plaintiffs' claims will not disturb federal-state comity principles under *Grable*. As set forth by Secretary Azar in his Fourth Amended Declaration: "Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declaration." Moreover, the plain, statutory language of the PREP Act expresses a strong federal interest and a clear intention to supersede or preempt state control of the issues raised by Plaintiff's Complaint.

71. Congress did not intend the application of PREP Act immunity to be decided by State Courts. As such, this Court would not be disturbing or infringing on any balance of State and

Federal judicial responsibilities by retaining jurisdiction. To the contrary, the plain language of the statute seeks to assert broad federal authority over the issues arising under the Act, and seeks to eliminate all semblance of State Court control. Secretary Azar's Fourth Amended Declaration makes explicitly clear that there is exclusive federal jurisdiction over lawsuits involving covered countermeasures, and that this "federal jurisdiction" is essential to the uniform provision of a national response to the COVID-19 pandemic and the PREP Act.

72. At all relevant times, Defendants in the present action, in its preparation and response to the COVID-19 outbreak, was acting at the specific instruction and oversight of the federal government, specifically the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, and the Center for Disease Control and Prevention in responding to a federal effort to address the ongoing national state of emergency. Defendants' actions were taken "in an effort to assist, or to help carry out, the duties or tasks" dictated by the CDC and CMS in responding to the COVID-19 pandemic.

73. Defendants' actions and conduct were taken due to unprecedented and "strong government intervention" which went beyond the "mere auspices of federal direction." *Fung v. Abex Corp.*, 816 F. Supp. 569, 572 (N.D. Cal. 1992).

74. Defendants were acting specifically at the direction and under the supervision of the United States government with respect to various countermeasures implemented to prevent and treat the COVID-19 virus, including following evolving and specific guidelines from CMS and CDC with respect to: (1) infection control policies and procedures; (2) PPE procurement; (3) PPE allocation; (4) admission and discharge of residents; (5) managing visitors and outside persons, (6) staffing allocation and retention; (7) isolation protocols and management, among multiple additional directives.

75. Defendants' response to the COVID-19 outbreak as it relates to Decedent, Emma Mitchell, was directly related to what they were asked to do by the federal government.

76. As previously set forth, Defendants assert that it is immune from liability in this matter under the PREP Act as they meet the requirements of "covered person" as contemplated by 42 U.S.C. § 247d-6d(i)(2)(B)(iv). Further, Defendants' actions specifically related to this claim constitute "covered countermeasures" pursuant to the PREP Act, which would qualify for and trigger immunity from liability for the purposes of the present suit.

X. ALL DEFENDANTS CONSENT TO REMOVAL

77. Defendants are the only defendants named in the state court action, therefore consent is not required to 28 U.S.C §1446(b).

XI. FILING OF REMOVAL PAPERS

78. Defendants are giving Plaintiff notice of this Notice of Removal pursuant to 28 U.S.C. §1446(d) by filing this Notice electronically with the Clerk of Court through the ECF System; the ECF System will send a Notice of Electronic Filing to Plaintiff upon filing.

79. Defendants will also file a copy of this Notice of Removal with the 17th Judicial District Court of Tarrant County, Texas where the state court action is currently pending as required by 28 U.S.C. §1446(d).

XII. NO WAIVER

80. Nothing in this Notice of Removal shall be interpreted as a waiver or relinquishment of Defendants' right to assert any defense or affirmative matter including, without limitation, the defenses of (1) lack of jurisdiction over a person; (2) improper venue; (3) insufficiency of process; (4) insufficiency of service of process; (5) failure to state a claim; or (6) any other procedural or substantive defense available under state or federal law.

81. Removal to federal court is proper in this case and the undersigned counsel for Defendants, has read the foregoing and signs this Notice of Removal pursuant to Rule 11 of the Federal Rules of Civil Procedures, as required by 28 U.S.C. § 1446(a).

XIII. ATTACHMENTS

82. Pursuant to LR 81.1 of the Local Rules of the Northern District of Texas the following documents are being filed with this Court as exhibits to this Notice of Removal:

Exhibit A Civil Cover Sheet

Exhibit B Supplemental Cover Sheet

Exhibit C Index of all process, pleadings, orders, and other filings in the state action are as required by 28 U.S.C. §1446(a)

- Exhibit C-1 Copy of the Case Summary/Docket Sheet in the State Action
- Exhibit C-2 Plaintiff's Original Petition
- Exhibit C-3 Plaintiff's Letter to the Court Requesting Citations
- Exhibit C-4 Civil Citations, Affidavit of Services and Return of Service
- Exhibit C-5 Defendants' Original Answer
- Exhibit C-6 Order Setting Trial
- Exhibit C-7 Defendants' First Amended Answer

Exhibit D Certificate of Interest Persons

Exhibit F Notice of Related State Case

83. Pursuant to Federal Rule of Evidence 201, Defendants also file with this Court Defendants' Request for Judicial Notice of the following documents:

Exhibit E Defendants' Request for Judicial Notice ("RFJN")

Exhibit E-1- Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision January 8, 2021, a true and correct copy of which is attached hereto as Exhibit "E-1."

Exhibit E-2 - March 10, 2020 Declaration of United States Health and Human Services Secretary Alex Azar invoking the Public Readiness and Emergency Preparedness Act for the COVID-19 pandemic effective February 4, 2020. A true and correct copy of this Declaration is attached hereto as Exhibit "E-2."

Exhibit E-3 - April 10, 2020, Amended Declaration of United States Health and Human Services Secretary Alex Azar extending liability immunity to additional covered countermeasures authorized under the Coronavirus Aid, Relief and Economic Security ("CARES") Act (i.e., NIOSH approved respiratory protective devices), effective March 27, 2020. A true and correct copy of Amended Declaration is attached hereto as Exhibit "E-3."

Exhibit E-4- June 4, 2020, Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, Federal Register, Vol. 85, No. 110. A true and correct copy of this Second Amended Declaration is attached hereto as Exhibit "E-4."

Exhibit E-5- December 3, 2020, Fourth Amendment to Declaration of Health and Human Services Secretary Alex Azar Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. A true and correct copy of this Fourth Amended Declaration is attached hereto as Exhibit "E-E-5."

Exhibit E-6 - August 14, 2020, Letter by Robert Charrow, General Counsel for the Office of the Secretary of the Department of Health and Human Services, to Thomas Barker of Foley Hoag, LLP. A true and copy of this letter is attached hereto as Exhibit "E-6."

Exhibit E-7 - Advisory Opinion 20-04, issued October 22, 2020 as amended October 23, 2020, by General Counsel Robert Charrow. A true and copy of this Opinion is attached hereto as Exhibit "E-7."

Exhibit E-8 - Department of Health & Human Services, Office of the Secretary, General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act and The March 10, 2020 Declaration Under the Act, April 17, 2020, as modified on May 19, 2020. A true and correct copy of this Advisory Opinion is attached hereto as Exhibit "E-8."

Exhibit E-9- List of Covered Countermeasures subject to Emergency Use Authorizations by the United States Food and Drug Administration. A true and correct copy of this List is attached hereto as Exhibit "E-9."'

Exhibit E-10 - January 8, 2020, CDC Health Update Outbreak of Pneumonia of Unknown Etiology (PUE) in Wuhan China, a true and correct copy of which is attached hereto as Exhibit "E-10."

Exhibit E-11 - January 17, 2020 CDC Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-n-coV) in a Healthcare Setting, a true and correct copy of which is attached hereto as Exhibit "E-11."

Exhibit E-12- January 24, 2020 CDC Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-n-coV) in a Healthcare Setting, a true and correct copy of which is attached hereto as Exhibit "E-12."

Exhibit E-13 - February 1, 2020 CDC Health Update and Interim Guidance on the Outbreak of 2019 Novel Coronavirus (2019-n-coV). A true and correct copy of which is attached hereto as Exhibit "E-13."

Exhibit E-14 - The Centers for Medicare and Medicaid Services ("CMS") February 6, 2020 Memorandum QSO 20-09-ALL instructing healthcare providers to adhere to CDC directives regarding the use of standard, contact and airborne precautions when interacting with PUI, a true and correct copy of which is attached hereto as Exhibit "E-14."

Exhibit E-15 - February 28, 2020, CDC Health Update and Interim Guidance on the Outbreak of 2019 Novel Coronavirus (COVID-19). A true and correct copy of which is attached hereto as Exhibit "E-15."

Exhibit E-16 - March 3, 2020, CDC Strategies to Prevent the Spread of COVID-19 in Long-Term Care Facilities (LTCF), a true and correct copy of which is attached hereto as Exhibit "E-16."

Exhibit E-17- March 4, 2020, CMS Memorandum Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes-QSO 20-14-NH, a true and correct copy of which is attached hereto as Exhibit "E-17."

Exhibit E-18 - March 8, 2020 CDC Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19), a true and correct copy of which is attached hereto as Exhibit "E-18."

Exhibit E-19 - March 10, 2020 CDC Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings. A true and correct copy of which is attached hereto as Exhibit "E-19."

Exhibit E-20 - March 10, 2020, CMS Memorandum QSO 20-17-ALL-Guidance for use of Certain Industrial Respirators by Health Care Personnel, a true and correct copy of which is attached hereto as Exhibit "E-20."

Exhibit E-21 - March 13, 2020 CMS Memorandum QSO-20-14-NH-Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes (REVISED), a true and correct copy of which is attached hereto as Exhibit "E-21."

Exhibit E-22 - March 17, 2020 CDC documents containing strategies for the optimizing the supply of eye protection, isolation gowns, N95 respirators and face masks, true and correct copies of which are collectively attached hereto as Exhibit "E-22."

Exhibit E-23 - March 20, 2020 CMS Memorandum QSO 20-20-ALL Prioritization of Survey Activities, a true and correct copy of which is attached hereto as Exhibit "E-23."

Exhibit E-24- March 21, 2020, CDC publication entitled "Preparing for COVID-19: Long-term Care Facilities Nursing Homes," a true and correct copy of which is attached hereto as Exhibit "E-24."

Exhibit E-25 - April 2, 2020 CMS COVID-19 Long Term Care Facility Guidance, a true and correct copy of which is attached hereto as Exhibit "E-25."

WHEREFORE, Defendants Advanced HCS, LLC (incorrectly identified as d/b/a Wedgewood Nursing Home); Wedgewood Rehab & Nursing GS, LLC; and TOM GS, LLC, respectfully removes this action from the 17th Judicial District Court of Tarrant County, Texas, to this Court pursuant to 28 U.S.C. §§ 1332, 1441, 1446, and provides Plaintiff of notice of same. Should any question arise as to the propriety of this removal, Defendants respectfully requests an opportunity to provide further briefing and oral argument.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 12th, 2021, a true and correct copy of the foregoing has been filed electronically with the Clerk of Court through ECF, and ECF will send a Notice of Electronic Filing to the following:

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